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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,106	07/31/2003	Dennis M. Brown	A-70245-2/RFT/THR	7746

7590 09/25/2006

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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/631,106	BROWN, DENNIS M.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-19 and 22-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-19 and 22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/15/06;6/30/06;8/18/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 15-19 and 22-25 are presented for examination.

Applicant's Amendment filed June 30, 2006 has been received and entered into the present application. Applicant's Information Disclosure Statements (IDS) filed May 15, 2006 (one page), June 30, 2006 (one page) and August 18, 2006 (one page) have each been received and entered into the application. As reflected by the attached, completed copies of form PTO/SB/08A (three pages total), the Examiner has considered the cited references.

Claims 15-19 and 22-25 remain pending and are under examination. Claims 20-21 are cancelled and claims 15-19 and 22-25 are amended.

Applicant's arguments, filed June 20, 2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Objection to the Specification

Insofar as Applicant has failed to address the following objection to the specification raised at page 4 of the previous Office Action dated March 24, 2006, the objection is repeated below for Applicant's reference:

The disclosure remains objected to because the paragraph at lines 17-31 of page 4 fails to conclude with a period.

Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-19 and 22-24 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of amonafide in conjunction with homoharringtonine for the treatment of fibrosarcoma, does not reasonably provide enablement for the treatment of solid tumors generally with the combination of amonafide with homoharringtonine, for the reasons already made of record at pages 9-16 of the previous Office Action dated March 24, 2006, of which said reasons are herein incorporated by reference.

Cancellation of claims 20-21 renders the present rejection **moot** as applied to such claims.

Applicant's remarks have been carefully considered in their entirety, but fail to be persuasive.

In response to the rejection set forth under 35 U.S.C. 112, first paragraph, as failing to provide enablement commensurate in scope with the presently claimed subject matter, Applicant states that some experimentation, even if complex, is allowable under 35 U.S.C. 112, first paragraph. Applicant relies upon the article of Twentyman et al. in support of the assertion that the RIF-1 fibrosarcoma model utilized in the presently disclosed examples has been used for decades as an established tumor model (see page 8 of Applicant's remarks).

However, Applicant is reminded of MPEP §2164.08, which directs that all questions of enablement must be evaluated against the claimed subject matter. Concerning the breadth of a

claim relevant to enablement, the only relevant concern is whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. The determination of the propriety of a rejection based upon the scope of a claim relative to the scope of enablement involves the determination of how broad the claim is with respect to the disclosure and the determination of whether one skilled in the art is enabled to use the *entire scope* of the claimed invention without undue experimentation.

It is here noted that Applicant has provided adequate and sufficient enabling direction in the instant disclosure for the combination of amonafide with homoharringtonine for the treatment of RIF-1, a type of murine fibrosarcoma. However, Applicant has failed to provide adequate enabling direction or guidance in the form of evidence, working examples, or persuasive and scientifically sound reasoning as to why this combination in a single discrete solid tumor type would be sufficiently representative of the same activity in the any one or more other solid tumor types presently claimed such that they would provide a basis for enabling the entire scope of the presently claimed invention.

It is in this regard that Applicant is reminded that a conclusion of a lack of enablement must take into consideration the unpredictability in the art at the time of the invention and the direction or guidance provided by Applicant. The amount of guidance required to be present in the specification as originally filed is directly proportional to the amount of knowledge in the art as well as the unpredictability in the art. In other words, if little or nothing is known in the prior art about an aspect of the claimed invention and the art is unpredictable, the specification needs more detail and guidance as to how to use the invention in order to be enabling. Please reference *In re Fisher*, 417 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) and *Chiron Corp. v. Genentech*

Inc., 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004). Applicant fails to address the unpredictability in the art either in the present disclosure or in response to the state of the art as presented by the Examiner in the previous Office Action. Rather, Applicant continues to state on the record that the working example is enabled and fully satisfies the requirements of 35 U.S.C. 112, first paragraph.

The enablement of the working example provided in the specification is not disputed. However, it is not representative of the breadth of the presently claimed subject matter. Applicant's claims broadly claim the use of amonafide and homoharringtonine for use in treating *any solid tumor*. The fact that Applicant has exemplified amonafide in combination with homoharringtonine for the treatment of only one type of solid tumor does not address the high degree of variability in the art in terms of the pathophysiological differences among all solid tumor types and their reactivity to different anticancer compounds, particularly when combined for adjuvant therapy. Applicant has also failed to provide any evidence, or describe any protocol, either in the present disclosure or in the accompanying remarks, that addresses this variability in the art such that one of ordinary skill in the art would have been imbued with at least a reasonable expectation of success in treating any solid tumor with a combination of amonafide and homoharringtonine based on the direction provided in the present specification.

It is here noted that the state of the art was such at the time of the invention that the results and effects seen with a single combination chemotherapeutic regimen in one type of solid tumor would not have been predictive of the same, or a substantially similar, level of efficacy seen in any solid tumor type because the art was aware of three distinctly different categories of solid tumors: (1) sarcomas, those that arise from connective or supporting tissues, such as bone

or muscle; (2) carcinomas, those that arise from glandular tissues and epithelial cells; and (3) lymphomas, those that arise from the lymphoid organs, such as the lymph nodes, spleen or thymus. Though each of these three types can be lumped under the umbrella category of "solid tumor", insofar as they are not "liquid tumor", i.e., blood cancers, such as leukemia, the distinct etiology and pathophysiological differences between these three categories of solid tumor would not have imbued the skilled artisan with a reasonable expectation of success in treating any one or more of these types of solid tumor when efficacy had only been demonstrated in a sarcoma (i.e., fibrosarcoma) murine model. In light of such, and further in light of the state of the art presented in the previous Office Action, it remains that the art is highly unpredictable with regard to the treatment of solid tumor.

Applicant, however, fails to rebut this presumption of unpredictability in the art by providing, by way of examples, guidance or persuasive scientific reasoning, as to why the working example of the present disclosure would have been predictive of the same level of efficacy over the breadth of the subject matter presently claimed. The question at hand is not whether RIF-1 murine fibrosarcoma is acceptable for use as a model, but rather *whether RIF-1 murine fibrosarcoma is a solid tumor model reasonable representative of the entire breadth of solid tumor*. Twentyman et al., however, fails to present any reasoning or suggestion that the RIF-1 fibrosarcoma model is representative of all solid tumor types. Rather, Twentyman et al. states, "In this paper, we describe a mouse tumor system that grows both in vivo and as clones in vitro, is nonimmunogenic or minimally immunogenic, and does not produce early spontaneous metastases. These characteristics make the system ideal for comparison of tumor response endpoints in the evaluation of different chemotherapy or radiotherapy regimens." (see second

paragraph, column 1, following the abstract, at page 595) Use of the model for testing and evaluation of different chemotherapy or radiotherapy regimens is not equivalent to the use of RIF-1 fibrosarcoma as a representative model of all solid tumors known in the art.

In light of such, it is maintained that one of ordinary skill in the art would be faced with the impermissible burden of undue experimentation in order to execute the entire scope of the subject matter presently claimed. The basis for the rejection is not simply that experimentation would be required, since it is clear from the state of the prior art and Applicant's disclosure and remarks that experimentation in this particular art is not at all uncommon, but that the experimentation required in order to practice this aspect of the invention would be *undue*. Please reference *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976), which states, "The test of enablement is not whether any experimentation is necessary, but whether, *if experimentation if necessary, it is undue*." (emphasis added) Although Applicant asserts that the experimentation would not require more effort than is normally required in the art (see page 8 of Applicant's remarks), it remains that the state of the art was such at the time of the invention that the high degree of unpredictability noted and recognized in the art with regard to the efficacious treatment of solid tumor precludes the extrapolation of the results seen in a single type of solid tumor (i.e., fibrosarcoma) to the larger and much more highly varied genus of any solid tumor type. In the absence of any direction or guidance presented by Applicant as to how such therapeutic objectives could be achieved without necessitating an undue level of experimentation, the present disclosure is viewed as lacking an enabling disclosure of the *entire scope* of the presently claimed subject matter.

For these reasons, and those previously made of record at pages 9-16 of the previous Office Action dated March 24, 2006, rejection of claims 15-19 and 22-24 remains proper and is **maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-19 and 22-25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Scheithauer et al. ("Phase II Study of Amonafide in Advanced Breast Cancer", *Breast Cancer Research and Therapeutics*, 20:63-67; 1991) in view of Jiang et al. ("Comparative *In Vitro* Antitumor Activity of Homoharringtonine and Harringtonine Against Clonogenic Human Tumor Cells", *Investigational New Drugs*, 1:21-25, 1983), each already of record, for the reasons of record set forth at pages 20-23 of the previous Office Action dated March 24, 2006, of which said reasons are herein incorporated by reference.

Cancellation of claims 20-21 renders the present rejection **moot** as applied to such claims.

Applicant traverses the rejection on the grounds that neither reference explicitly or implicitly provides any suggestion or motivation to use amonafide in conjunction with homoharringtonine because a myriad of possible agents exist that could be used in conjunction with amonafide and that there is no motivation or suggestion to select homoharringtonine from

hundreds of possible anticancer agents. Applicant states that the lack of motivation fails to provide a reasonable expectation of success.

Applicant's remarks have been carefully considered in their entirety, but fail to be persuasive.

First, Applicant is reminded that an express motivation to combine is not required to be explicitly stated in the prior art in order to construct a finding of obviousness. Please reference MPEP §2145(X), which states, "However, there is no requirement that an express, written motivation to combine must appear in the prior art references before a finding of obviousness."

Regardless, however, Applicant appears to have ignored the implicit suggestion to combine the references in light of the knowledge generally available to one of ordinary skill in the art at the time of the invention. As stated by Applicant:

"The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solves as a whole would have suggested to those of ordinary skill in the art." *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000)."

Applicant's argument that there is no implicit motivation to combine amonafide with homoharringtonine because the myriad of possible agents that could be used in conjunction with amonafide is sufficiently great that, absent any motivation or suggestion to specifically pick homoharringtonine, there is no reasonable expectation of success, is not persuasive. The implicit motivation to combine amonafide with homoharringtonine results directly from the fact that each of amonafide and homoharringtonine were recognized in the art to have significant anti-tumor activity in breast cancer and also that Scheithauer et al. provides an *explicit* suggestion to use

amonafide in combination chemotherapeutic regimens for the treatment of breast cancer. The very fact that each was known in the art to have the same therapeutic utility raises the reasonable expectation of success that the two agents, when combined or used in conjunction, either in a method of treating breast cancer, or in a composition for use in treating breast cancer, would have, at minimum, additive, if not synergistic, antitumor effects when combined.

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980): "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art. The fact that a first component is in no way related to the second component, but where each has the same utility, does not detract from the obviousness of combining them. *In re Linder*, 457 F.2d 506, 507 (CCPA 1972). (Holding that it would have been obvious to combine two known dispersants, since one skilled in the art would have expected a mixture of such dispersants to also be a dispersant). Moreover, picking and choosing known components from several references, each which itself discloses a plurality of such components, is permissible where each component has the same individual utility. *In re Dial*, 326 F.2d 430 (CCPA 1964). (Holding that it would have been obvious to have combined four individual stabilizers for halogenated hydrocarbon solutions from three different references, where there was no evidence in the record establishing that Applicant's claimed combination of stabilizers was any more effective or in any way otherwise different in

inhibiting the decomposition of halogenated hydrocarbons than any single member of that combination. Id at 432.)"

In light of such reasoning, it remains that the use of amonafide in conjunction with homoharringtonine for use in a method of treating a solid tumor, i.e., breast cancer, or for use in a composition, would have been *prima facie* obvious to one of ordinary skill in the art.

Additionally, the fact that Applicant argues patentable distinction over the fact that the present invention claims a physical combination of agents where Scheithauer et al., at best, teaches the administration of the two agents separately, such is Applicant's interpretation of the reference and ignores the fact that the phrase "combination chemotherapy" would have naturally suggested to the skilled artisan both regimens wherein the agents were administered in conjunction with one another or were administered together in a single dosage form. Furthermore, it is noted that the present method claims merely require that the two agents are "in conjunction", but does not require that they be physically combined.

For these reasons, and those previously made of record at pages 20-23 of the previous Office Action dated March 24, 2006, rejection of claims 15-19 and 22-25 remains proper and is **maintained**.

Double Patenting

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Rejections Withdrawn

The rejection of claims 15-24 over the method claims of U.S. Patent No. 6,630,173; the allowed method claims of U.S. Patent Application No. 11/067,074; and the method claims of U.S. Patent Application No. 10/625,866; have each been obviated by Applicant's amendments to the present claims and are hereby **withdrawn**.

Rejections Pending

Claims 15-19 and 22-24 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting over copending claims 50-59 of U.S. Patent Application No. 10/976,961, already of record, for the reasons of record set forth at pages 24-26 of the previous Office Action dated March 24, 2006 and further in view of the following remarks:

Applicant traverses the present provisional rejection on the grounds that the copending claims are directed to a method of treating a subject with cancer comprising the step of administering to the subject an effective amount of an amonafide analog, where the present

claims are directed to a method for treating solid tumors comprising the administration of amonafide in conjunction with homoharringtonine.

The present rejection remains proper because the present method of treating a solid tumor anticipates the therapeutic objective of the copending claims (i.e., treating cancer), and the administration of amonafide and homoharringtonine in the present claims clearly anticipates the administration of amonafide in the copending claims. Applicant argues that the copending claims are directed to the use of an amonafide analog; however, the copending claims clearly provide for the administration of amonafide itself.

In light of such reasoning, and further in light of the fact that Applicant has failed to submit a Terminal Disclaimer, the present provisional rejection of claims 15-19 and 22-24 under the judicially created doctrine of obviousness-type double patenting remains proper and is **maintained**.

Claim 25 remains provisionally rejected under the judicially created doctrine of obviousness-type double patenting over copending claims 42-44 of U.S. Patent Application No. 10/976,961, already of record, for the reasons of record set forth at pages 24-26 of the previous Office Action dated March 24, 2006 and further in view of the following remarks:

Applicant traverses the present provisional rejection on the grounds that the copending claims are directed to a pharmaceutical composition comprising a naphthalimide analog, where the present claims are directed to a composition comprising amonafide and homoharringtonine.

However, the copending claims clearly provide for a pharmaceutical composition comprising amonafide itself in combination with a carrier or diluent, which is clearly anticipated

by the presently claimed composition of amonafide and homoharringtonine. Although the present claims do not explicitly state that the composition is a "pharmaceutical", such a characteristic is inherent because the composition is intended for use in treating proliferative diseases, which would require the composition to be pharmaceutically acceptable in order to be administered to patients. Additionally, though the copending claims recite the use of a carrier or diluent, the use of such would have been *prima facie* obvious to one of ordinary skill in the art because such components were commonly used during the process of formulating pharmaceuticals and the use of such would have naturally commended itself to the skilled artisan.

In light of such reasoning, and further in light of the fact that Applicant has failed to submit a Terminal Disclaimer, the present provisional rejection of claim 25 under the judicially created doctrine of obviousness-type double patenting remains proper and is **maintained**.

Conclusion

Rejection of claims 15-19 and 22-25 remains proper and is **maintained**.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

September 6, 2006

Ardin H. Marschel 9/16/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER